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10/539,399	10/03/2006	Henry William Lupton	LRM-36144-A-US	4662

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EXAMINER	
PANI, JOHN	
ART UNIT	PAPER NUMBER
3736	

NOTIFICATION DATE	DELIVERY MODE
02/03/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/539,399	LUPTON, HENRY WILLIAM	
	Examiner	Art Unit	
	JOHN PANI	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54,55,57-67 and 69-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54,55,57-67 and 69-85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/2/2010 has been entered.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 70 requires "reinforcing member having a proximal end and a distal end, and extending along and being perpendicular to one of the flat major surfaces of the distal portion of the guide wire from the proximal end of the distal portion to a location on the distal portion axially spaced apart from the distal end of the distal portion to define with the distal end of the distal portion the guide portion". Claim 78 requires "reinforcing member having a proximal end and a distal end, and extending along, and being perpendicular to, one of the flat major surfaces of the distal portion of the guide wire". The specification does not mention that the reinforcing member is perpendicular to anything, let alone being in these claimed configurations.

Claim Objections

3. Claim 82 and 83 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 82 and 83 are identical to claims 75 and 76, respectively.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 54, 55, 57-67, and 69-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 70 requires "reinforcing member having a proximal end and a distal end, and extending along and being perpendicular to one of the flat major surfaces of the distal portion of the guide wire from the proximal end of the distal portion to a location on the distal portion axially spaced apart from the distal end of the distal portion to define with the distal end of the distal portion the guide portion". It is unclear what is meant by a "reinforcing member . . . being perpendicular to one of the flat major surfaces". The reinforcing member is described in the original disclosure as being a three-dimensional structure with several surfaces and edges. It is unclear whether a

limitation of "reinforcing member . . . being perpendicular to one of the flat major surfaces" requires that, for example, all surfaces and edges of the reinforcing member are perpendicular to a flat major surface, merely that some aspect of the reinforcing member could be described as "perpendicular to one of the flat major surfaces", or some other configuration. This lack of clarity regarding the metes and bounds of the claim renders claim 70 and its dependent claims indefinite. For purposes of interpretation with respect to prior art, the limitation has been interpreted to require that some aspect of the reinforcing member could be described as "extending along and being perpendicular to one of the flat major surfaces of the distal portion of the guide wire from the proximal end of the distal portion to a location on the distal portion axially spaced apart from the distal end of the distal portion".

7. Claim 78 requires "reinforcing member having a proximal end and a distal end, and extending along, and being perpendicular to, one of the flat major surfaces of the distal portion of the guide wire". The reinforcing member is described in the original disclosure as being a three-dimensional structure with several surfaces and edges. It is unclear whether a limitation of "reinforcing member . . . being perpendicular to, one of the flat major surfaces" requires that, for example, all surfaces and edges of the reinforcing member are perpendicular to a flat major surface, merely that some aspect of the reinforcing member could be described as "perpendicular to, one of the flat major surfaces", or some other configuration. This lack of clarity regarding the metes and bounds of the claim renders claim 78 and its dependent claims indefinite. For purposes of interpretation with respect to prior art, the limitation has been interpreted to require

that some aspect of the reinforcing member could be described as "extending along, and being perpendicular to, one of the flat major surfaces of the distal portion of the guide wire".

8. Claim 85 requires "the reinforcing member defines a central plane which coincides with the central minor plane". The reinforcing member is described in the original disclosure as being a three-dimensional structure with several surfaces and edges. It is unclear whether a limitation requiring the above requires that some surface of the "reinforcing member" lies along a central plane that coincides with the central minor plane, that the "reinforcing member" has some edge/line that partially defines the central plane and coincides with the central minor plane, that some central plane through the reinforcing member coincides with the central minor plane, or some other configuration. This lack of clarity regarding the metes and bounds of the claim renders claim 85 indefinite. For purposes of interpretation with respect to the prior art, the limitation has been interpreted to require that some central plane through the reinforcing member coincides with the central minor plane.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 54, 55, 57-67, and 69-85 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

11. Claim 70 requires "reinforcing member having a proximal end and a distal end, and extending along and being perpendicular to one of the flat major surfaces of the distal portion of the guide wire from the proximal end of the distal portion to a location on the distal portion axially spaced apart from the distal end of the distal portion to define with the distal end of the distal portion the guide portion". Claim 78 requires "reinforcing member . . . being perpendicular to, one of the flat major surfaces of the distal portion of the guide wire". The original disclosure does not explicitly, implicitly, or inherently disclose that at the time of the invention the Applicant possessed these limitations. The Applicant points to paragraph [0059] of the application as support for this limitation. However, this paragraph merely states that "reinforcing member 38 coincides with the central minor plane 34, and extends axially along the major surface 29 from the proximal end 26 and terminates at 40". Paragraph [0058] notes that "the minor surfaces 31 and 32 define a central minor plane 34 midway between the minor surfaces 31 and 32, and perpendicular to the central major plane 33". However, this does not imply or require that the reinforcing member is perpendicular to one of the flat major surfaces. In at least one interpretation of claims 70 and 78, it appears that the claims require that all surfaces and edges of the reinforcing member are perpendicular to the major flat surface. However, Fig. 5 clearly shows this is not a characteristic of the invention. Therefore claims 70 and 78 and their dependents lack sufficient written description in the original disclosure.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 54, 55, 57-67, and 69-85 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat. No. 7,083,577 to Osawa et al. ("Osawa").

14. Osawa teaches:

In reference to Claim 70

A guide wire (1) for use in a surgical or other procedure for accessing a remote site in a body of a human or animal subject (col. 1 lines 5-7), the guide wire defining a longitudinally extending axis (see Fig. 10), and terminating at one end in a proximal portion (proximal end in Fig. 10), and at an opposite end in a distal portion (23) for accessing the remote site, the distal portion having a proximal end and a distal end and being of rectangular transverse cross-section (see Fig. 8C) defining a pair of opposite major flat surfaces (the thin, flat surfaces that angle inward in Fig. 8B and are shown face on in Fig. 8C; see annotated figures below), joined by a pair of opposite minor surfaces (the triangular surface facing out of the page in Fig. 8B, and matching opposite surface; see annotated figures below), and terminating adjacent the distal end thereof in

a guide portion (portion of 23 from left --i.e. distal-- end as depicted in Figs. 8B,C to the beginning of middle step of the three stepped portions), the guide portion being adapted to be shaped to a desired curved configuration for facilitating guiding of the guide wire into a branched vessel of the subject (see col. 7 lines 31-40), and an elongated reinforcing member (middle step) located on the distal portion of the guide wire for minimizing axial twisting of the distal portion between the proximal end of the distal portion and the guide portion thereof (see col. 4 lines 50-65), the reinforcing member having a proximal end and a distal end and extending along and being perpendicular to one of the flat major surfaces (note that lines extending perpendicularly to the flat major surface in the view of Fig. 8-B can be drawn, and these lines would lie on the longitudinally extending sides of the reinforcing member defined above; in other words, the reinforcing member extends in directions perpendicular to the flat major surface, and this characteristic extends along the reinforcing member's length; this limitation is thus determined to read on Osawa; please see annotated view of Fig. 8B below – perpendicularity of added lines is an approximation) of the distal portion of the guide wire from the proximal end of the distal portion to a location on the distal portion axially spaced apart from the distal end of the distal portion to define with the distal end of the distal portion the guide portion (see Figs. 8A-C).

Fig.8-B

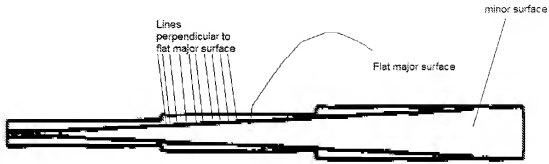
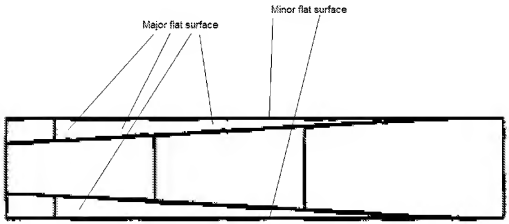

Lines perpendicular to flat major surface
Flat major surface
minor surface

Fig.8-C


Major flat surface
Minor flat surface

In reference to Claim 78

A guide wire (1) for use in a surgical or other procedure for accessing a remote site in a body of a human or animal subject (col. 1 lines 5-7), the guide wire defining a longitudinally extending axis (see Fig. 10), and terminating at one end in a proximal portion (proximal end in Fig. 10), and at an axially opposite end in a distal portion (23) for accessing the remote site, the distal portion having a proximal end and a distal end, and being of rectangular transverse cross-section (see Fig. 8C) defining a pair of opposite major flat surfaces (the thin, flat surfaces that angle inward in Fig. 8B and are shown face on in Fig. 8C; see annotated figures above), joined by a pair of opposite minor surfaces (the triangular surface facing out of the page in Fig. 8B, and matching opposite surface; see annotated figures above), the minor surfaces defining a central minor plane midway between the minor surfaces (see Fig. 8-C), and the major flat surfaces terminating adjacent the distal end thereof in a guide portion portion of 23 from left --i.e. distal-- end as depicted in Figs. 8B,C to the beginning of middle step of the three stepped portions), the guide portion being adapted to be shaped to a desired curved configuration for facilitating guiding of the guide wire into a branched vessel of the subject (see col. 7 lines 31-40), and an elongated reinforcing member (middle step) located on the distal portion of the guide wire for minimizing axial twisting of the distal portion between the proximal end of the distal portion and the guide portion thereof (see col. 4 lines 50-65), reinforcing member having a proximal end and a distal end, and extending along, and being perpendicular to, one of the flat major surfaces of the distal portion of the guide wire (note that lines extending perpendicularly to the flat major

surface in the view of Fig. 8-B can be drawn, and these lines would lie on the longitudinally extending sides of the reinforcing member defined above; in other words, the reinforcing member extends in directions perpendicular to the flat major surface, and this characteristic extends along the reinforcing member's length; this limitation is thus determined to read on Osawa; alternatively/additionally, the distal and proximal edges of the middle step are perpendicular to the outer edges of the major flat surface; please see annotated view of Fig. 8B above – perpendicularity of added lines is an approximation) and extending from the proximal end of the distal portion to a location on the distal portion axially spaced apart from the distal end of the distal portion to define with the distal end of the distal portion the guide portion (see Figs. 8A-C).

In reference to Claim 54

A guide wire as claimed in claim 70 (see above) in which the major flat surfaces of the distal portion define a central major plane located midway between the major surfaces, and the minor surfaces of the distal portion define a central minor plane located midway between the minor surfaces (see Figs. 8A-8C).

In reference to Claim 55

A guide wire as claimed in claim 70 (see above) in which a reinforcing member is located on each major flat surface (Figs. 8A-8C).

In reference to Claims 77 and 84

A guide wire as claimed in claims 70 and 78 (see above) in which the reinforcing member extends from the major flat surface of the distal portion of the guide wire to a longitudinally extending edge, the longitudinally extending edge extending from the

proximal end of the reinforcing member to the distal end of the reinforcing member (see Fig. 8A).

In reference to Claim 57

A guide wire as claimed in claim 54 (see above) in which the reinforcing member extends parallel to the central minor plane (i.e. radially).

In reference to Claim 58

A guide wire as claimed in claim 54 (see above) in which the reinforcing member extends at an angle greater than zero degrees to the central minor plane (the raised surfaces have extensions at various non-zero angles with respect to the central minor plane).

In reference to Claim 59

A guide wire as claimed in claim 77 (see above) in which the reinforcing member defines opposite longitudinally extending sides (portions of step visible in Fig. 8B), the opposite longitudinally extending sides of the reinforcing member terminating along the longitudinally extending edge of the reinforcing member (Fig. 8A).

In reference to Claim 60

A guide wire as claimed in claim 59 (see above) in which the opposite longitudinally extending sides of the reinforcing member are parallel to each other (note that the stepped portions found on the two sides could be considered a single reinforcing member, and their opposite longitudinally extending sides are parallel, see Fig. 8B).

In reference to Claim 61

A guide wire as claimed in claim 70 (see above) in which the reinforcing member is integrally formed with the distal portion (see Fig. 8A) of the guide wire.

In reference to Claim 62

A guide wire as claimed in claim 70 (see above) in which the distal portion of the guide wire extends through a sleeve (**3**), and a first securing means (**4**) at the distal end thereof secures the distal portion to the sleeve, the first securing means defining the distal end of the guide wire (see Fig. 10).

In reference to Claim 63

A guide wire as claimed in claim 62 (see above) in which the first securing means is shaped to form a dome shaped distal end of the guide wire (see Fig. 10) for facilitating passage of the guide wire smoothly through a vessel of the subject.

In reference to Claim 64

A guide wire as claimed in 62 (see above) in which the guide portion is located between the reinforcing member (see Fig. 8A) and the first securing means (see Fig. 10)

In reference to Claim 65

A guide wire as claimed in claim 62 (see above) in which the first securing means comprises a solder joint, an adhesive joint, or a brazed joint (see col. 7 lines 58-60).

In reference to Claim 66

A guide wire as claimed in claim 62 (see above) in which the sleeve extends in a proximal direction beyond the proximal end of the distal portion along a portion of the guide wire (see Fig. 10), and that a proximal end of the sleeve is secured to the guide

wire by a second securing means that comprises an adhesive joint, solder joint, or a brazed joint (see col. 7 lines 55-60).

In reference to Claim 67

A guide wire as claimed in claim 70 in which the guide wire is substantially torsionally rigid between the distal portion and the proximal portion of the guide wire for minimizing axial twisting of the guide wire between the proximal portion and the guide portion (see col. 4 lines 50-65).

In reference to Claim 69

In combination a catheter (see col. 1 lines 5-7) and the guide wire as claimed in claim 70 (see above).

In reference to Claims 71 and 79

A guide wire as claimed in claims 70 and 78 (see above) in which the reinforcing member extends in a generally axial direction (see Fig. 8A).

In reference to Claims 72 and 80

A guide wire as claimed in claim 70 and 78 (see above) in which the major flat surfaces of the distal portion converge towards each other towards the distal end of the distal portion (see Fig. 8B).

In reference to Claims 73 and 85

A guide wire as claimed in claims 54 and 78 (see above) in which the reinforcing member coincides with the central minor plane (Fig. 8A).

In reference to Claims 74 and 81

A guide wire as claimed in claims 70 and 78 (see above) in which the reinforcing member extends adjacent one of the minor surfaces (see Fig 8A).

In reference to Claims 75 and 82

A guide wire as claimed in claim 59 (see above) in which the opposite longitudinally extending sides of the reinforcing member converge towards the longitudinally extending edge of the reinforcing member for defining the longitudinally extending edge as a longitudinally extending ridge (see Fig. 8A, viewed head on, the step is a ridge).

In reference to Claims 76 and 83

A guide wire as claimed in claim 59 in which the longitudinally extending edge of the reinforcing member converges towards the distal portion adjacent the distal end of the reinforcing member (see Fig. 8A).

Response to Arguments

15. Applicant's arguments filed 9/2/2010 have been fully considered but they are not persuasive. In reference to Applicant's arguments that Osawa does not disclose "that the 'reinforcing member' is 'perpendicular to one of the flat major surfaces of the distal portion of the guide wire'", the Examiner respectfully disagrees for the reasons detailed in the statement of rejection above. In reference to Applicant's arguments that Osawa does not disclose "'the reinforcing member' to terminate at a location which is 'axialy spaced apart from the distal end of the distal portion to define with the distal end of the distal portion the guide portion'", the Examiner respectfully disagrees. The middle step

of Osawa is defined as the "reinforcing member" above, and as is shown in Figs. 8A-C, this step clearly terminates in the claimed manner, as it stops where the left-most step begins, and the left-most step is located on the distal portion of the guide portion as defined above. This division at least defines the proximal extent of the left-most step, or "guide portion".

16. Applicant's arguments that the Examiner's interpretation of Osawa "requires the 'reinforcing member' to be in the same plane as 'the flat major surfaces of the distal portion of the guide wire'" are not found persuasive. The Examiner does not see any reason why this is "required", and believes the Applicant may have misunderstood the previous rejection. The Examiner has included annotated drawings above in the interest of clarifying the Office's position.

17. Applicant's arguments that Osawa does not "minimiz[e] axial twisting of the distal portion" are not found persuasive, because Osawa discloses all of the claimed structural features, and appears to be quite structurally similar to the overall disclosed invention of Applicant. Additionally, regarding the argument that "Osawa et al. permits . . . to be bent and to flex in a direction perpendicular to the central major plane", the Examiner notes that the claim does not forbid this capability.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN PANI whose telephone number is (571)270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JP/ 1/28/11

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736